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February 11, 2004

OVERNIGHT COURIER 02/11/04

Dockets Management Branch
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Amendment to Citizen Petition
Docket Number 2003P-0505/CP1
Amendment for Inclusion of Pediatric Waiver Request

Dear Sir or Madam:

The petition cited above was submitted on October 30, 2003. The petition requested the Commissioner of the Food and Drug Administration to declare that the drug product, Acetaminophen, Caffeine and Orphenadrine Citrate Tablets, in two strengths of 770 mg / 60 mg / 50 mg and 385 mg / 30 mg / 25 mg, respectively, were suitable for submission in an abbreviated new drug application. On February 4, 2004, we received a letter from the Office of Generic Drugs stating that the review of the petition cannot continue until it can be determined whether the requirement for pediatric studies may be waived.

The Agency referenced the provisions of the Pediatric Research Equity Act of 2003, which amended the Federal Food, Drug and Cosmetic Act, to provide the Agency authority to require drug firms to study certain drugs in pediatric patients if the Agency felt that such study would provide beneficial health data for that patient population. In that regard, please consider this amendment to the petition requesting such a waiver.

The act provides a provision for a waiver from such requirement if:

> (iii) the drug or biological product;
>
> (I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and
>
> (II) is not likely to be used in a substantial number of pediatric patients.

The petitioner hereby requests that a waiver from the conduct of pediatric patient be granted for the approval of this petition to permit subsequent ANDA filing.

The reference-listed drug product is a tablet that contains a dose of aspirin that represents an equipotent dose of the proposed acetaminophen component. This product is used for the treatment of symptomatic relief of mild to moderate pain associated with musculoskeletal

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disorders. The innovator product, according to its currently approved labeling, is not indicated for the treatment of pediatric patients. The proposed product will contain the same warnings and recommendations against use in the pediatric population.

Based on the use and nature of the reference-listed drug (RLD) and the proposed product, the change in active ingredient to include an equipotent dose of acetaminophen substituted for aspirin would not likely change the use of the product or make it any more likely to be used in pediatric patients. In addition, because of the dose of acetaminophen (770 mg) in the full-strength tablet and the lack of experience with orphenadrine, the limitations of use and indications described in the labeling of the RLD make it unlikely that the proposed product would be appropriate for use, or in any case, would not be used in a substantial number of pediatric patients. Also, it is noted that there are currently other alternatives available to treat this condition in pediatric patients, and thus, the proposed drug product does not provide a meaningful benefit over existing therapies for pediatric patients. To further support the contention that products for musculoskeletal pain or muscle relaxant products are typically not used in the pediatric population, there were no such products contained on the FDA's list of drug products for which additional pediatric information may product health benefits in the pediatric population.

For the reasons stated above and consistent with the provisions of the Pediatric Research Equity Act of 2003, the petitioner respectfully requests that this waiver be granted. Due to the fact that this ANDA Suitability Petition has been pending for greater than 90-days, the undersigned requests that the review of this waiver request be conducted in an expeditious manner.

Sincerely,

Robert Pollock

Robert W. Pollock
Vice President
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RWP/pk

cc: Emily Thomas (Office of Generic Drugs)
Martin Shimer (Office of Generic Drugs)

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